

**REMARKS**

Claims 7-13 and 25-45 are pending in the instant application. Claims 7-12, 14, 18, 26 and 29 have been canceled. Claims 13, 21, 25, 28 and 32 have been amended. Support for the amendment may be found, for example, at page 15, lines 20-30 and in Figure 18. Additional support for the amendments to the claims may be found throughout the specification, including the originally filed claims. *No new matter has been added.* Any amendments to and/or cancellation of the claims was done solely to more particularly point out and distinctly claim the subject matter of Applicant's invention in order to expedite the prosecution of the application. Applicant reserves the right to pursue the claims as originally filed in this or a separate application(s).

Applicant thanks the Examiner for removing several of the rejections from the prior Office Action and for entering the amendments to the claims and specification.

***Priority***

The Examiner has refused to accept Applicants' priority claim to provisional application 60/165,189, filed on 11/12/99. Specifically, the Examiner alleges that the provisional application does not disclose the instantly claimed expression vector combination and has not disclosed expression vectors with HBEGF.

Applicant asserts that the instant application is entitled to the priority date of the provisional application, 11/13/00. Support for expression vectors comprising a promoter of interest, a nucleic acid encoding HBEGF, a nucleic acid encoding GFP and an internal ribosome entry site (IRES) is found throughout the provisional specification, for example, pages 13-14, page 16 (bottom), pages 17-18 and page 33. It would thus be readily apparent to one skilled in the art that the presently claimed constructs could be constructed from the variety of disclosed components. Accordingly, Applicant requests that the Examiner reconsider the priority date and accept Applicant's priority claim.

***Rejection of Claims 21-24 and 38-45 Under 35 U.S.C. §112, 2<sup>nd</sup> Paragraph***

The Examiner has rejected claim 21 as having insufficient antecedent basis because it allegedly recites the limitation "the first and second selection genes" in line 4 without any antecedent basis. Applicant respectfully draws the Examiner's attention to lines 1 and 2 of claim 21, which reads in relevant part "An expression vector comprising: *a first and second selection gene....*" However, the Applicants have amended claim 21 to include articles before all occurrences of the word "second". Accordingly there is proper antecedent basis for the limitation "the first and the second selection genes" in line 4 of claim 21.

The Examiner has rejected claim 32 as improperly reciting a claim limitation incompatible with that of the limitations of claim 31 from which it is dependent. Applicant has amended claim 32 to correct the improper dependency.

The Examiner has rejected claim 38 as having insufficient antecedent basis because it allegedly recites the limitation “the first and second selection genes” in line 4 without any antecedent basis. Applicant respectfully draws the Examiner’s attention to lines 1 and 2 of claim 38, which reads in relevant part “An expression vector comprising *a first and a second selection gene* ....” However, the Applicants have amended claim 21 to include articles before all occurrences of the word “second”. Accordingly there is proper antecedent basis for the limitation “the first and second selection genes” in line 4 of claim 38.

Applicant thus respectfully requests reconsideration and withdrawal of the foregoing rejections.

#### ***Joint Inventorship***

The Examiner has alleged that this application currently names joint inventors. However, this application only names one inventor, Todd M. Kinsella. Accordingly, Applicant has no duty to point out the inventor and invention dates of claims that are not commonly owned.

#### ***Rejection of Claims 13, 15, 16, 17, 19, 20, 30, and 32 Under 35 U.S.C. §103(a)***

The Examiner has maintained the rejection of claims 13, 15, 16, 17, 19, 20, 30, and 32 under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,613,563 B1 (Sosnowski *et al*) and U.S. Patent 6,465,253 (Wickham, *et al.*).

Applicants respectfully traverse the rejection. To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention and would have had a reasonable expectation of success in making the claimed invention. Under section 103, "[b]oth the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (*Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.* 927 F.2d 1200, 1207, 18 USPQ2d 1016 (Fed. Cir. 1991), quoting *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed Cir. 1988)). Moreover, when a combination of references are used to establish a *prima facie* case of obviousness, the Examiner must present evidence that one having ordinary skill in the art would have been motivated to combine the teachings in the applied references in the proposed manner to arrive at the claimed invention. See, e.g., *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985). Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations (M.P.E.P. 2143).

Even if a combination of prior art references teaches or suggests all of the claim limitations, no *prima facie* case of obviousness may be established without a motivation to combine. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. *Id.* The level of skill in the art cannot be relied upon

to provide the motivation to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

Applicants have amended independent claims 13, 25 and 28 to include a CD9 gene in the claimed vectors. Neither U.S. Patent No. 6,465,253 nor 6,613,563 teach or suggest the use of a CD9 gene in any of the disclosed vectors. Thus, there is no motivation to combine these references to produce a vector comprising a CD9 gene, and the references when combined do not produce the claimed invention. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-832-1000

Respectfully submitted,

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